



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/945,166	08/31/2001	David R. Elmaleh	MGA-003.01	1584
25181	7590	09/21/2006	EXAMINER	
FOLEY HOAG, LLP PATENT GROUP, WORLD TRADE CENTER WEST 155 SEAPORT BLVD BOSTON, MA 02110			VIVLEMORE, TRACY ANN	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/945,166

Applicant(s)

ELMALEH ET AL.

Examiner

Tracy Vivlemore

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 25-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 25-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any rejection or objection not reiterated in this Action is withdrawn.

Response to arguments: Claim Rejections - 35 USC § 112

Claims 1-8, 10, 11 and 25-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. This rejection is maintained for the reasons set forth in the office action mailed February 22, 2006.

Applicant traverses the new matter rejection by arguing the disclosure of a single species of construct that does not cross the blood brain barrier is sufficient to describe the genus of constructs encompassed by the claims. To support this argument applicant states that it is well known in the art that very few delivery systems allow for effective delivery of therapeutic molecules across the blood brain barrier and that the skilled artisan recognizes that most agents are strictly limited from crossing it; therefore there is not substantial variation within the claimed genus. While applicant is correct that many therapeutic molecules are unable to cross this barrier, some do, therefore not crossing the blood brain barrier is not an inherent feature of all therapeutic molecules. The specification as filed does not explicitly contemplate constructs having essentially

no ability to cross the barrier, therefore the limitation introduces new matter by attempting to limit the claims to something not specifically contemplated as part of the invention. The specification doesn't provide a description of what makes a construct have "essentially no ability" to cross the blood brain barrier. The specification provides a single example of something that doesn't cross the barrier, but does not provide description of the essential structure that provides the function of making the construct not cross the barrier. Without this description, one of skill can't immediately envision which constructs would and would not cross the barrier.

Claim Rejections - 35 USC § 102

Claims 1, 4, 5, 8, 10, 11, 25-28, 30-32 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuijpers et al (of record). This rejection is maintained for the reasons set forth in the office action mailed February 22, 2006.

Claims 1-3 and 5-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Kayyem et al. (of record). This rejection is maintained for the reasons set forth in the office action mailed February 22, 2006.

Applicant traverses the rejections over Kuijpers et al. and Kayyem et al. by arguing that claims are anticipated only if a single reference discloses every element of the claims. Applicant further argues that the examiner has improperly relied on other references and therefore Kuijpers et al. and Kayyem et al. do not teach all limitations of the claims. Applicant's arguments are not persuasive because the use of Moffett et al. and Opalinska et al. is not an improper reliance on additional references for anticipation, but to demonstrate that Kuijpers et al. and Kayyem et al. provide a disclosure of

Art Unit: 1635

features that are not explicitly stated but are inherently present. This reliance on additional references is supported by the MPEP in section 2131.01:

Extra Reference or Evidence Can Be Used To Show an Inherent Characteristic of the Thing Taught by the Primary Reference

"To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (The court went on to explain that "this modest flexibility in the rule that 'anticipation' requires that every element of the claims appear in a single reference accommodates situations in which the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges." 948 F.2d at 1268, 20 USPQ at 1749-50.).

Claim Rejections - 35 USC § 103

Claims 1, 4, 5, 8, 10, 11 and 25-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuijpers et al. as applied to claims 1, 4, 5, 8, 10, 11, 25-28, 30-32 and 34 above, and further in view of Gewirtz et al. (of record) and Low et al. (of record). This rejection is maintained for the reasons set forth in the office action mailed February 22, 2006.

Applicant traverses the 103 rejection by asserting the examiner has provided no motivation to combine the cited references. This argument is not persuasive because the previous action clearly sets forth a motivation for combining the references at page 7:

"Because Kuijpers et al. teach a construct for targeting tumor cells and because Low et al. and Gewirtz et al. teach that C-myb is useful in treating cancers, one of ordinary skill in the art would have been motivated to target a C-myb antisense sequence to a tumor using the construct of Kuijpers et al. in order to obtain enhanced delivery of the sequence to tumor cells."

Applicant's arguments regarding the lack of teaching of all limitations is based on the alleged lack of teaching that the constructs of Kuijpers et al. do not cross the blood brain barrier. However, as stated above, the constructs of Kuijpers et al. inherently

possess the characteristic of not crossing the blood brain barrier. Therefore, the assertion by the applicant that the combination of the references doesn't teach all limitations of the claims is incorrect.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The central FAX Number is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now

Art Unit: 1635

contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance.

Representatives are available to answer your questions daily from 6 am to midnight

(EST). The toll free number is (866) 217-9197. When calling please have your

application serial or patent number, the type of document you are having an image

problem with, the number of pages and the specific nature of the problem. The Patent

Electronic Business Center will notify applicants of the resolution of the problem within

5-7 business days. Applicants can also check PAIR to confirm that the problem has

been corrected. The USPTO's Patent Electronic Business Center is a complete service

center supporting all patent business on the Internet. The USPTO's PAIR system

provides Internet-based access to patent application status and history information. It

also enables applicants to view the scanned images of their own application file

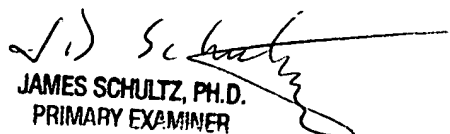
folder(s) as well as general patent information available to the public. For more

information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore
Examiner
Art Unit 1635

TV
September 8, 2006


JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER